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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/361,630	07/27/1999	CHARLES S. ZUKER	2307E- 084210	5750

909 7590 08/13/2002

PILLSBURY WINTHROP, LLP
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MCLEAN, VA 22102

EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

22

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/361,630

Applicant(s)

ZUKER ET AL.

Examiner

Ulrike Winkler, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 99-102 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 99-102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The request filed on June 17, 2002 (Paper No. 21) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/361630 is acceptable and a CPA has been established. An action on the CPA follows.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Amendment filed June 17, 2002 (Paper No. 21) in response to the Office Action of June 15, 2001 (Paper No. 14) is acknowledged and has been entered. Claims 1-35 and 37-98 have been cancelled. Claims 99-102 have been added and are currently being examined.

The Office has noted that Applicant has cancelled all claims including method claims (Groups VI and VII as set out in the Restriction/ Election requirement of Paper No. 8) which may be entitled to rejoinder should the product claim (the nucleic acid) be allowed. Applicant is hereby advised that a rejoinder of claims is possible at a later date if the product is eventually found patentable. Guidance on treatment of product and process claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b) is set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86.

To facilitate examination under § 103, where product and process claims are presented in the same application, applicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined. In the event of rejoinder, the rejoined process claims

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will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

Claim Rejections - 35 USC § 101 and 35 USC § 112

The prior rejection is **maintained** for reasons of record of under 35 U.S.C. 101, newly added claims 99-102 are now rejected for the same reasons because the claims are drawn to the same subject matter. The claims are rejected under of under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Applicant's arguments have been fully considered but are not found to be persuasive. Applicant's main argument is that the sequences would be useful as pharmacological tools. Therefore, the nucleic acids of the present invention are useful, e.g., as taste cell specific probes and markers, because the nucleic acids and the proteins that they encode are specifically expressed in specialized taste cells of the tongue (see, e.g., specification, page 6. 15-19). Neither the specification as filed nor the art disclose any activity for the protein Tcp2 such that a utility would be well established. At best, the specification merely indicates that Tcp-2 exhibits specific or preferential expression in taste buds (page 55, line 9-11). Each nucleic acid sequence that is expressed within a multicellular organism is expressed in some cell type and this expression is regulated in either a temporal or spatial manner. That, is, each expressed sequence is expressed in some cell type at some point in a hosts lifetime. Some transcripts are expressed embryonically, others are expressed only in particular cells, while still others are expressed in a wide variety of cells. In addition, some transcripts which are expressed in particular cells are only expressed in response to certain metabolic or environmental stimuli. For example, heat

shock proteins may only be expressed in particular tissues or cells when they are subject to certain environmental stresses but are otherwise not expressed. Therefore, each nucleic acid will generally have the characteristic of being expressed in some cell type under some condition. As such, the protein has not been characterized in regards to its biological function or properties to identify the protein as a receptor, part of the g-protein transduction signal complex or an ion channel. Since the sequences are not associated with any disease and the biology of the Tcp-2 protein has not been established (ie. how does the brain perceive the stimulus should the protein become activated), utilizing these compounds in food and pharmaceutical industries would not define it as a substantial utility.

The prior rejection is **maintained** for reasons of record of under 35 U.S.C. 112, first paragraph, newly added claims 99-102 are now rejected for the same reasons because the claims are drawn to the same subject matter. Applicant's arguments have been fully considered but are not deemed persuasive. In regard to the lack of specific utility, it is noted that each nucleic acid sequence has certain inherent properties such as its sequence and its expression pattern. These are biological characteristics of a given nucleic acid. The elucidation of an inherent property of a given nucleic acid without some indication as to how this particular and specific property would be used is not considered to be specific. For example, a living cell and a dead cell may be distinguished based upon expression of RNA since dead cells would be expected to lose the ability to express genes. Further, each cell type would be expected to have an array gene expression that relates to its function. However, the mere characterization of nucleic acids expression in a given cell without some indication of the function of these nucleic acids would not be considered to impute a specific utility. Without knowing what the nucleic acids and

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ultimately the protein products do, for example perceive salt, sweet, bitter or sour there is no substantial utility for the nucleic acids. There is no evidence that these proteins are even involved in taste perception, all that has been established by the specification is that these proteins are preferentially expressed in taste buds. Since there is no specific utility associated with Tcp-2 one of skill in the art would not know how to use the invention without undue experimentation.

Claim Rejections - 35 USC § 112

The rejection of claims 32-35, 37- 40, 46, 47 and newly added claims 95 and 98 for reasons U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is withdrawn** in view of applicant cancellation of the original claims. Applicant's newly amendment claims do not make reference to 70% homology; therefore the enablement rejection is withdrawn.

Conclusion

No claims are allowed.

SEQ ID NO: 3, 4, 12 and 13 are apparently free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Ulrike Winkler, Ph.D.

James C. House
8/9/02

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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